

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <b>THIS DOCUMENT RELATES TO:  WAVE 1 CASES ATTACHED ON EXHIBIT A</b>	<b>Master File No. 2:12-MD-02327  MDL No. 2327  JOSEPH R. GOODWIN  U.S. DISTRICT JUDGE</b>
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**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE CERTAIN OPINIONS OF DR. SHELBY THAMES**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames ("Dr. Thames"). In support of their Motion, Plaintiffs state as follows:

**INTRODUCTION**

Dr. Shelby Thames has a Doctorate in Organic Chemistry and has previously testified before this Court in the *Jo Huskey v. Ethicon* matter. However, he now seeks to offer several opinions in defense of Ethicon's Prolene-based meshes that are either based on evidence that does not exist or that have no scientific basis. No jury should hear any expert testimony that is not reliable. And since it is just Dr. Thames' that holds these opinions—without any support—they should be excluded.

In addition, Dr. Thames' not only disagrees with the scientific literature, and Ethicon's own internal oxidation studies, regarding whether Ethicon's Prolene material oxidizes inside the body—but he also disagrees with himself on several occasions. In some parts of his report, he

describes evidence of Prolene oxidation, and in others he states that he has seen no evidence of it. As such, Dr. Thames' self-contradictory opinions are unreliable on this matter and should be limited or excluded entirely.

Finally, Dr. Thames' cleaning protocol for explanted meshes is fundamentally flawed because he did not perform a proper control to test if this cleaning process, itself, was destroying evidence of oxidized Prolene. This fact is established by his own testimony. And the flaws in his cleaning protocol render all of his testing and analysis of Plaintiffs' meshes completely unreliable.

### **STANDARD OF LAW**

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed.R.Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Thames to proffer expert testimony and “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Thames is qualified and the testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, Dr. Thames can only offer testimony that is “fit” for the case, and there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Id.*

### **ARGUMENT**

When Dr. Thames testified before this Court in the *Huskey v. Ethicon* matter, his opinions focused on whether or not he saw evidence of Prolene oxidation and degradation in several peer-reviewed publications.<sup>1</sup> The opinions described in his report for the Wave 1 cases, however, present several new areas of testimony that were not addressed previously. As explained below, many of his opinions are not reliable and his testimony should be limited or excluded entirely.

#### **I. Dr. Thames’ oxidation opinions are at conflict with the available evidence—and with themselves.**

Dr. Thames’ Wave 1 expert report is at conflict with itself. First, he states “I believe that Ethicon’s Prolene material used in its mesh products does not undergo meaningful or harmful degradation *in vivo*,” and that this opinion is bolstered by the seven year dog study performed by Ethicon scientist Dan Burkley.<sup>2</sup> However, that dog study specifically concluded that “[d]egradation in PROLENE is still increasing [over time *in vivo*] and PVDF, even though a few

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<sup>1</sup> *Huskey v. Ethicon* trial, Day 7 at 74-91, Exhibit B

<sup>2</sup> Dr. Thames Wave 1 General report at 6 Exhibit C,

cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking.”<sup>3</sup>

Dr. Thames’ report, puzzlingly, goes on to state that “[a]t the time of this writing, I have seen no scientifically sound evidence to prove Ethicon’s Prolene mesh oxidizes *in vivo*.”<sup>4</sup> This opinion is in direct conflict with what was found in the Burkley dog study. If Dr. Thames is going to hold an opinion that Prolene does not oxidize *in vivo*, then he should not be relying on a study that specifically concludes that surface degradation is taking place after implantation. As such, his opinion that Prolene oxidation does not take place *in vivo* should be excluded.

## **II. Dr. Thames misstates the evidence from the dog study in order to fit his opinions.**

Next, Dr. Thames’ report states that the “seven year data confirmed no *significant* difference in molecular weights for the 4/0 Prolene control suture and the seven year explants”—which is almost verbatim what the results of Mr. Burkley’s dog study stated.<sup>5</sup> Importantly, however, the results of that dog study do not state that there were no changes in molecular weight—they state that there were changes, but that Mr. Burkley did not consider them to be *significant*. Mr. Burkley confirmed this fact at his deposition.<sup>6</sup>

However, even with this admission of *in vivo* losses in Prolene’s molecular weight, page 9 of Dr. Thames’ report goes on to state:

“Burkley’s study is further supported by the work of plaintiffs’ expert, who performed molecular weight determinations of 16 explants of Prolene. The plaintiff’s expert report was consistent with that of Burkley as **neither found molecular weight losses** for the explants.

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<sup>3</sup> ETH.MESH.05453719, Exhibit D

<sup>4</sup> Dr. Thames Wave 1 General report at 13., Exhibit C

<sup>5</sup> *Id.* at 6 (emphasis added)

<sup>6</sup> Deposition of Dan Burkley, May 22, 2013 at 154:22-155:1, Exhibit E

These data are consistent with **no molecular weight changes** after 7 years implantation.

...

Burkley's 7 year dog study findings are consistent with the following data in that

- Prolene's **molecular weight did not change** over the 7 years of implantation"<sup>7</sup>

None of this is true. There is absolutely *no evidence* that Prolene's molecular weight was unchanged in Mr. Burkley's dog study—in fact, all of the evidence states that there were losses *in vivo*. Dr. Thames misstates the evidence to fit his opinions in this case, and this kind of opinion testimony can never be allowed at trial. Any testimony by Dr. Thames that Prolene does not lose molecular weight *in vivo* should be excluded.

**III. Dr. Thames cannot determine “improved toughness” from the tensile testing data collected from the dog study—so any related opinions should be excluded.**

Similarly, Dr. Thames opines that the data collected from the seven year dog study “validates toughness improvement after initial implantation.”<sup>8</sup> This is also not true. Dr. Thames cannot make any determinations regarding the toughness of these explanted sutures because the data required for those determinations was *never recorded*. Plaintiffs need not look any further than Dr. Thames' own report for truth of this.

**Figure 5** from Dr. Thames' report illustrates how the “toughness” of a material can be determined by plotting the amount of stress placed on a material against the amount of strain measured, and the “[t]oughness is defined as the area under the stress-strain curve.”<sup>9</sup> Dr. Thames' report, however, contains no stress-strain curve from the dog study, nor does it contain the underlying data needed to plot such a curve—because that data was never collected.

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<sup>7</sup> Dr. Thames Wave 1 General report at 9 (emphasis added) Exhibit C

<sup>8</sup> *Id.* at 7

<sup>9</sup> *Id.*

Instead, **Figure 6** of Dr. Thames' report plots the suture break strength on the Y-axis against the percent elongation on the X-axis.<sup>10</sup> This is clearly a "break strength-percent elongation curve", not a stress-strain curve—and this is simply not how "toughness" is measured, which was the whole point of Dr. Thames' **Figure 5**.<sup>11</sup> Just as Dr. Thames took liberties with the dog study's conclusions regarding losses in molecular weight, he offers a similarly baseless opinion about increased toughness—because the data that is needed for his claimed opinion was never recorded in the dog study. As such, any testimony regarding an "increased toughness" found in the dog study should be excluded.

#### **IV. Dr. Thames' additional unsupported opinion testimony must be excluded.**

Two of Dr. Thames' opinions regarding explanted mesh have no basis in the scientific method, nor do they have any backing in the peer-reviewed literature—they are simply inadmissible *ipse dixit* opinions. First, he opines that he sees translucent flakes on explanted blue fibers of Prolene, and because they are translucent, he believes that they are protein and not degraded polypropylene. But Dr. Thames cannot cite to any literature or support for that opinion:

Q. And then you have identified one portion from a clear suture that has a translucent flake; is that right?

A. Yes, sir, correct.

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<sup>10</sup> *Id.* at 8

<sup>11</sup> Plaintiffs' expert Dr. Guelcher agrees that toughness cannot be determined from Figure 6 in Dr. Thames' report: "I need to see the actual stress-strain curve. I need to know the stress at 1 percent elongation, 5 percent elongation, 10 percent, until it breaks. And from that stress-strain curve, you can do more analysis. But this is simply a plot of break strength versus elongation at break. And I – I can't make those kinds of inferences that you're trying to get me to agree to." Exhibit F, Dr. Guelcher Wave 1 deposition at 184:6-15

Q. So that was the first part of what I'm asking you. The second part of what I'm asking you is, do you have anything to back up the fact that -- what you've just found?

A. I think I have described it as efficiently as I am capable of describing it.

Q. But you don't have any research to back it up?

A. What is your definition of "research"?

Q. Something in a peer review.

A. Peer review?

Q. Yes.

A. Sir, we do research to put stuff in the peer review. Not everything that's researched is in the peer review.

Q. I understand that. But you don't have anything in a peer review to support what you're stating in this report for Ms. Stubblefield; is that right?

A. Peer review? This will go in the literature to be peer reviewed. But, **no, this is my finding**, and I think it's very clear and that most anyone will be able to understand it. Because not only do we find this here, we find it in 19 other cases just like this.<sup>12</sup>

Dr. Thames also seeks to proffer completely unsupported opinions about the presence of extrusion lines on explanted mesh:

Q: With respect to your SEM opinions, do you have anything in a peer review literature that would support the opinion that the extrusion lines would degrade along with the outer surface of the Prolene fiber?

A. If there was oxidation of Prolene, it is my opinion that extrusion lines would be interfered with. They are not here. **I have not seen that written in another document, is my belief.** And you can see the extrusion lines being maintained all the way from an SEM -- well, about one, but certainly three. And you can see the transverse cracking and extrusion lines are still there.<sup>13</sup>

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<sup>12</sup> Dr. Thames deposition for the Stubblefield case at 47:3-48:18 (objections omitted) (emphasis added), Exhibit G.

<sup>13</sup> Dr. Thames deposition for the Daino case at 29:13-30:1, Exhibit H

Q: Your report at the top of page 12 states, “If the surface of the Prolene fibers had degraded as postulated by plaintiff’s expert, the extrusion lines would degrade during this process and would no longer be visible. That is not the case we observed.” Do you see that?

A. Yeah.

Q. Can you tell me any support for that statement that you might have?

A. **That’s my belief.**<sup>14</sup>

Regardless of what Dr. Thames *believes* to be true, if he cannot substantiate or support those beliefs in any meaningful scientific way, they should not be heard by any jury. *Daubert*, 509 U.S. at 590 (in the context of Rule 702, knowledge “connotes more than subjective belief or unsupported speculation.”). His testimony must be relevant and reliable, and he has the burden to prove that it is admissible. *Maryland Cas. Co.*, 137 F.3d at 783. He has not shown that either of these opinions is reliable or scientifically sound. As such, any testimony about the presence of clear or colored flakes on explanted mesh, or about the presence of extrusion lines on explanted mesh, should be excluded.

**V. The flaws in Dr. Thames’ cleaning protocol for explanted meshes render all of the data he collected and opinions that he holds unreliable, and “of no significance.”**

Dr. Thames seeks to opine that none of the mesh explants he examined showed signs of oxidation, but his testing—and any related testimony—should be excluded because Dr. Thames’ cleaning protocol would have likely destroyed any evidence of oxidation that existed on those meshes. And Dr. Thames’ cleaning protocol did not even perform a proper control to determine if the cleaning methods he chose would destroy evidence of oxidized polypropylene.

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<sup>14</sup> Dr. Thames deposition for the Stubblefield case at 84:15-25, Exhibit G

Dr. Thames admitted the importance of running a proper control; as he told plaintiffs' counsel: "[n]o control, your data is of no significance."<sup>15</sup> That is exactly the situation we have here—his data is of no significance, and it should be excluded in its entirety.

Q. Your cleaning procedure actually involves a few more things than just water, heat and bleach, --

A. Yes.

Q. -- in all fairness, doesn't it?

A. Yes, sir. We use protein to -- which in the event there's still clean protein, it will help remove some of it. It's an enzyme called Proteinase K, P-R-O-T-E-I-N-A-S-E-K, I believe.

Q. So you used some Proteinase K?

A. Yes, sir. It's an enzyme.

Q. And what does that do?

A. **Well, it helps open the proteins and the flesh more so that if there's any carbonyl groups that are there that haven't been removed, they're taken away.** It's just another cleaning process basically, a little bit more rigorous. But it's an enzyme. It's a mild enzyme, but it works a different way.<sup>16</sup>

Yet according to Dr. Thames, the presence of carbonyl groups on explanted mesh *is what you would find* if you had evidence of oxidation.<sup>17</sup> But he chose to clean Plaintiffs' meshes with an enzyme that would destroy that very evidence. Even worse, Dr. Thames did not run a control of purposefully oxidized polypropylene through his cleaning protocol to test *if* it would destroy evidence of oxidation on Plaintiffs' meshes:

Q. So with respect to the FTIR that we're looking at, I've already given you two ranges, one where a hydroxyl group would be and one where a carbonyl is. Did you run a control where you had a piece of Prolene that had a hydroxyl group on

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<sup>15</sup> Dr. Thames General Deposition at 52:24-25, Exhibit I

<sup>16</sup> Dr. Thames General Deposition at 61:16-62:9, Exhibit I

<sup>17</sup> Dr. Thames General Deposition at 46:12-48:19, Exhibit I

it or had a carbonyl on it and run it through your protocol to make sure that your protocol did not destroy that oxidized Prolene?

A. I ran an exemplar of Prolene and found that nothing changed on its surface during this period of time, which means that, therefore, if there was something on the explant, it would still be there when I finally got through step five, that I would not have removed it, and it would still be there.<sup>18</sup>

...

Q. What I mean to say is that for any one of the steps, we're talking about the -- let's just stick with the Proteinase K. Did you put -- did you purposefully oxidize Prolene and then put it through that step of the cleaning process?

A. No, sir.

Q. And did you do that with any of the steps of the cleaning process?

A. No, sir.<sup>19</sup>

What Dr. Thames did by employing this cleaning protocol was to run a rigged game.

According to Dr. Thames, Proteinase K takes away carbonyls, but carbonyls are also what would be present on the mesh if it was oxidized.<sup>20</sup> Hence, his cleaning protocol would never have been able to find evidence of mesh oxidation—even if it initially existed on the meshes that he examined. This renders any testimony about the plaintiff-specific examinations he performed completely unreliable and, as Dr. Thames himself would say, “of no significance.”<sup>21</sup> As such, he should not be allowed to testify about any opinions rendered from this case-specific testing at trial.

### **CONCLUSION**

For the foregoing reasons, Dr. Thames should be limited in what he can testify about in these Wave 1 cases. No jury should ever hear any evidence that is unreliable—and the *ipse dixit*

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<sup>18</sup> Dr. Thames Deposition in the Stubblefield case at 64:7-23, Exhibit G

<sup>19</sup> Dr. Thames Deposition in the Daino case at 21:3-16, Exhibit H

<sup>20</sup> Dr. Thames General Deposition at 46:12-48:19 and 61:16-62:9, Exhibit I

<sup>21</sup> Dr. Thames General Deposition at 47:3-10; 52:24-25, Exhibit I

and factually unsupported statements by Dr. Thames complained about in this brief should be precluded. In addition, he has no basis to offer any case-specific opinions because his cleaning protocol likely destroyed whatever evidence of oxidation was originally on the meshes that he examined. Plaintiffs respectfully request their Motion be granted.

Dated: April 21, 2016

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace

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